

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION**

RECKITT BENCKISER
PHARMACEUTICALS, INC., RB
PHARMACEUTICALS LIMITED, and
MONOSOL RX, LLC,

Plaintiffs,

v.

BIODELIVERY SCIENCES
INTERNATIONAL, INC.,

Defendant.

Civil Action No. 5:13-CV-760-BO

**DEFENDANT’S REPLY
MEMORANDUM IN SUPPORT OF
ITS MOTION TO STAY PENDING
INTER PARTES REVIEW**

I. INTRODUCTION

Defendant BDSI¹ respectfully submits this Reply Memorandum in Support of Its Motion to Stay Pending Inter Partes Review, in response to Plaintiffs' Opposition to Defendant's Motion to Stay (D.I. 40, "Plaintiffs' Opposition" or "Plaintiffs' Opp."). Plaintiffs' Opposition suffers from the same defect plaguing the entirety of this action – it is premised on a speculative set of circumstances which may never occur. In contrast, the actual facts before the Court favor staying this action pending PTO review of the sole patent-in-suit.

Plaintiffs claim to be prejudiced by a stay because BDSI has applied for (but not yet received) FDA approval for a potentially competitive product, Bunavail™. BDSI's aspiration to obtain FDA approval and launch its product does not equate to FDA approval, nor even increase the likelihood of FDA approval. Accordingly, Plaintiffs' claims of actual or presumed prejudice resulting from a stay fail because BDSI is presently "off the market."

Plaintiffs likewise fail to demonstrate that the *inter partes* review (IPR) process will not simplify issues in the case. Plaintiffs argue that they will litigate claims 1-14 of the '832 Patent, which are not currently the subject of an IPR request. While this argument has some superficial appeal, the IPR on claims 15-19 will nonetheless simplify this action and narrow the disputed issues. Perhaps more importantly, Plaintiffs cannot credibly assert claims 1-14 against BDSI because information in the public domain establishes that the pH of BDSI's Bunavail™ is well outside the range of "about 3 to about 3.5 in the presence of saliva" as required by claims 1-14. The "threatened" assertion of these claims is a red herring and should be disregarded as such.

Even assuming that Plaintiffs persist in asserting claims 1-14, all of the factors relevant to

¹ Capitalized terms not defined herein shall have the same meaning ascribed to them in BDSI's January 31, 2014 Memorandum In Support of its Motion to Stay Pending *Inter Partes* Review (D.I. 34) ("BDSI's Opening Memorandum" or "BDSI Op. Mem."). All exhibits referenced herein are attached to the Declaration of Lynne Borchers, filed herewith.

the stay analysis favor staying this action. There are mechanisms to address concerns of future prejudice to Plaintiffs if and when they ripen. There is simply no legitimate reason for this litigation to move forward at this time.

II. ARGUMENT

A. A Stay Should Enter Because Plaintiffs' Claim of "Substantial and Undue Prejudice" is Nothing More Than Speculation

The infringement allegations in this case, all based on a set of future and speculative events, belie any "substantial and undue prejudice" that plaintiffs attempt to claim. Based on the record actually before the Court, BDSI and Plaintiffs are not competitors and while that could change in the future, a stay is nonetheless appropriate now.

The undisputed facts are that: (1) BDSI is precluded from launching Bunavail™ unless and until FDA approves Bunavail™; (2) FDA has not yet approved Bunavail™; and (3) BDSI aspires to obtain FDA approval and market Bunavail™. However, it is clear that aspirations do not always come to fruition,² and aspirations do not constitute patent infringement or direct competition. *See Eli Lilly & Co. v. Medtronic, Inc.*, 915 F.2d 670, 673 (Fed. Cir. 1990) ("A threat of sale does not constitute an act of infringement") (citing *Lang v. Pacific Marine and Supply Co., Ltd.*, 895 F.2d 761 (Fed. Cir. 1990)); *D.G. Rung Indus., Inc. v. Tinnerman*, 626 F. Supp. 1062, 1065 (W.D. Wash. 1986) ("There is no patent infringement under 35 U.S.C. § 271 when plaintiff alleges only intent and capability").³ That BDSI "seeks to obtain FDA approval for a proposed product that would directly compete with" Suboxone Film, *see* Declaration of Javier Rodriguez, D.I. 41-1 at ¶ 8 (filed by Plaintiffs on March 7, 2014) (emphasis added), does not give rise to substantial and undue prejudice in staying this action.

² *See, e.g.*, Exh. 8 (July 26, 2012 Navidea Biopharmaceuticals Press Release announcing credit facility in anticipation of the launch of LymphoseekII, the application for which was then-pending before FDA); Exh. 9 (September 10, 2012 Navidea Biopharmaceuticals Press Release announcing that FDA declined to approve LymphoseekII).

³ This is precisely why BDSI has moved to dismiss Plaintiffs' purported declaratory judgment claim.

The fact that Plaintiffs have not moved for a preliminary injunction only reinforces the propriety of the stay. If Plaintiffs believed they were being subjected to competitive harm presently, presumably they would have sought relief from the Court shortly after they filed this action in October 2013—almost six months ago. In addition, the cases that Plaintiffs rely upon regarding prejudice to the non-movant in the case of direct competitors (*Otto Bock*, *Davol*, *UltaTech*, *Avago*, discussed below) are not applicable to the instant case, because there is presently no direct competition between the parties. For at least these reasons, there is no “presumption” of prejudice, nor any actual prejudice. *See generally* BDSI Op. Mem. at 7-12 (establishing lack of prejudice to Plaintiffs in staying this action). As noted previously, delay alone does not constitute prejudice. *See* BDSI Op. Mem. at 7 (citations omitted).

Indeed, BDSI has acted with efficiency and diligence so that Plaintiffs cannot complain of prejudice. After learning of Plaintiffs’ Complaint, BDSI promptly prepared and filed its IPR request within a matter of months, and promptly moved to stay thereafter, making this case the “poster child” for a stay. BDSI is entitled to have the validity of claims 15-19 resolved in the less expensive and specialized forum offered by the PTO. *See, e.g., Capriola Corp. v. LaRose Indus., LLC*, 8:12-CV-2346-T-23TBM, 2013 WL 1868344, at *3 (M.D. Fla. Mar. 11, 2013) (unpublished) (noting that because key issues fall within the PTO’s expertise, “prudence commends resort to a stay until either the PTO declines review or ... the PTO grants and completes review to the benefit of the parties, the court, and the public”); *Progressive Cas. Ins. Co. v. Safeco Ins. Co. of Illinois*, No. 1:10CV01370, 2013 WL 1662952, at *7 (N.D. Ohio April 17, 2013) (unpublished) (noting that the expertise of the PTO “will refine the issues and create a record that would inform, assist, and expedite any subsequent litigation in this Court”); *Star Envirotech, Inc. v. Redline Detection, LLC*, No. SACV 12–01861, 2013 WL 1716068, at *2

(C.D. Cal. April 3, 2013) (unpublished) (“The Court finds that IPR is a procedure that aids in that enforcement of patent rights while streamlining the issues in need of litigation”); *Core Laboratories, LP v. Spectrum Tracer Services, L.L.C.*, No. CIV–11–1157–M, 2013 WL 501347, at *2 (W.D. Okla. Feb. 8, 2013) (unpublished) (noting that many courts grant stays “because the PTO is considered to have expertise in deciding patent infringement issues and tends to settle patent validity disputes more quickly and less expensively”); *Hill-Rom Services, Inc. v. Stryker Corp.*, No. 1:11–cv–1120–JMS–DKL, 2012 WL 5878087, at *6 (S.D. Ind. Nov. 20, 2012) (unpublished) (“the burden on the parties and the Court will be significantly reduced after the PTO applies its specialized expertise to the claims on reexamination”).

Plaintiffs’ arguments about the prejudice inherent in the length of the stay are misplaced. While Plaintiffs are correct that any party to the ‘832 Patent IPR may pursue an appeal to the Federal Circuit following conclusion of the IPR at the PTO, the other party would be free to seek to lift the stay at that time (*e.g.*, if claims 15-19 are upheld as patentable, Plaintiffs could seek to lift the stay and proceed with the litigation at that time).⁴ The potential for a Federal Circuit appeal thus does not change the propriety of a stay in this case as it stands now. Moreover, Plaintiffs have the ability to expedite the PTAB’s determination as to whether to institute the IPR, which will result in the IPR proceeding more quickly if instituted:

A patent owner seeking a shortened period for such a determination may wish to file a patent owner preliminary response well before the date the patent owner preliminary response is due, or file a paper stating that no patent owner preliminary response will be filed...

⁴ It bears noting that if litigation were to resume at the conclusion of the IPR at the PTO but before the resolution of any appeal to the Federal Circuit, the parties and the Court would likely have the benefit of the “final” PTO determination before proceeding to summary judgment or trial in this action, which would undercut the risk of inconsistent determinations and other woes encountered when proceeding in parallel tracks.

Federal Register Vol. 77, No. 157 Tuesday, August 14, 2012, p. 48689. The Director must decide whether to institute an IPR within three months of such filing. *Id.* at 48682. Additionally, Plaintiffs could seek expedited treatment if they are concerned about the timing of the resolution of the IPR. *See SAP America, Inc. v. Versata Development Group, Inc.*, Case CBM2012-00001 (MPT), at 1-2 (PTAB June 11, 2013) (attached as Exh. 10) (final written decision issued within 9 months after expedited treatment sought and granted by PTAB). Plaintiffs can hardly complain of prejudice caused by the likely timing of the IPR proceeding when Plaintiffs can proactively expedite that proceeding but have declined to do so.

Last but not least, Plaintiffs' argument that the "prejudice...is further compounded by the fact that the IPR only involves one of the three independent claims of the patent-in-suit..." (Plaintiffs' Opp. at 11) is neither supported in law nor fact. As a matter of law, Courts routinely stay actions where fewer than all patents/claims are being reviewed by the PTO. *See, e.g., e-Watch, Inc. v. Lorex Canada, Inc.*, C.A. No. H-12-3314, 2013 WL 5425298, at *7-9 (W.D. Tex. Aug. 9, 2013) (unpublished) (noting that even though only three of four patents were submitted for IPR, a stay will streamline issues, lower costs, and conserve resources); *Robert Bosch Healthcare Sys., Inc. v. ExpressMD Solutions, LLC*, No. C 12-00068, 2013 WL 752474, at *4 (N.D. Cal. Feb. 27, 2013) (unpublished) (granting stay despite no PTO review of some patents and some claims because "there is no requirement that reexamination resolve all issues in a case in order to warrant a stay"); *see also Synchronoss Tech., Inc. v. Asurion Mobile Appl'ns, Inc.*, Nos. 11-5811 (FLW), 11-6713(PGS), 2013 WL 1192266, at *6 (D.N.J. March 22, 2013) (unpublished) ("[T]here is no requirement that a reexamination resolve all the issues or even most of the issues in a case ... even though reexamination only addresses a percentage of the claims of the asserted patents, the Court finds that the analysis provided by the PTO in

construing those claims will provide valuable guidance to the Court”); *Progressive Cas. Ins. Co.*, 2013 WL 1662952, at *4-*8 (“that the PTAB may not address every single ground of invalidity and every art reference that might be raised in federal court, does not mean CBM review will not drastically simplify the issues presented to the Court. If a claim is invalidated or amended, it will not matter whether the PTAB addressed every ground of invalidity”). Thus, a stay is appropriate even though claims 1-14 have not (yet) been submitted to the PTO.⁵

As a factual matter, Plaintiffs cannot assert infringement of claims 1-14 of the ‘832 Patent in good faith.⁶ Claims 1-14 require a pH of “about 3 to about 3.5 in the presence of saliva.” See ‘832 Patent, claims 1-14 at col. 23, l. 58 to col. 24 l. 55. The pH of saliva is admitted to be 6.5 by Plaintiffs in the patent-in-suit. See *id.* at col. 11, l. 49 (“saliva (which has a pH of about 6.5)”). The pH of the Bunavail™ device, as reported in the publicly-available Declaration of Niraj Vasisht, Ph.D., submitted under 37 CFR § 1.132 to the PTO, is between about 5.8 and 6.2. See Exh. 11 ¶ 5.⁷ Thus, in contrast to the pH of 3 to 3.5 required by claims 1-14, the local pH “of the carrier matrix immediately surrounding the active ingredient as the matrix hydrates and/or dissolves...in the mouth of the user” (‘832 Patent col. 3, ll. 35-38) of Bunavail™ can be no less than about 5.8, and can only be higher than that as the device comes into contact with saliva of a higher pH of 6.5.

It would be objectively baseless for Plaintiffs to contend that a pH of 5.8 falls within the

⁵ BDSI may file a second IPR regarding claims 1-14, especially if Plaintiffs persist in the assertion of claims 1-14 of the ‘832 Patent.

⁶ Plaintiffs’ February 24, 2014 Opposition to Defendant’s Motion to Stay (D.I. 40) is the first time Plaintiffs have expressed an intent to assert claims 1-14 of the ‘832 Patent against BDSI.

⁷ The pHs provided for the individual layers are not the pH of the device. During dissolution, the various components (e.g., the ionic polymers and the various buffers used in each layer), interact and result in a device pH between about 5.8 and about 6.2 as explained in paragraph 6 of the Declaration. Those pHs are well above “about 3 to about 3.5.” Even if the pH of the layers represented the device pH, the claimed range is still 10 times more acidic than that observed in either layer, without even accounting for any effect of the higher-pH saliva.

claimed range. First, the pH scale is logarithmic such that each whole pH value is 10 times more acidic than the next highest value. Thus, even a change of 0.1 in value of pH is significant. In the instant case, the difference between a pH of about 3.5 (the upper limit claimed by the ‘832 patent) is over 100 times more acidic than a pH of about 5.8 (which should be well below the pH of the Bunavail™ device in saliva). Second, the claimed pH range was added, and then narrowed, during prosecution to obtain allowance of the ‘832 patent, and thus Plaintiffs are undeniably estopped from asserting that the claims extend beyond the stated pH range.⁸ Given that the pH of the Bunavail™ device of 5.8 – over 100 times more basic than a pH of “about 3.5” – is combined with saliva of an even higher pH of 6.5, and that Plaintiffs are estopped from enlarging the claimed range, there is no credible basis for them to assert that a pH associated with Bunavail™ falls within the range of claims 1-14. To the extent Plaintiffs were unaware of this pH data, they are certainly aware of it now and cannot justify seeking to litigate claims 1-14, much less preclude a stay on the basis of claims that they cannot assert in good faith.

For these reasons and for the reasons set forth in BDSI’s Opening Memorandum, there is no prejudice to Plaintiffs in staying this action, and therefore a stay is appropriate.

B. A Stay Will Simplify the Issues To Be Litigated

There is a high likelihood that the PTO will institute the IPR, thus simplifying issues in the litigation. Recent statistics demonstrate that the PTAB continues to institute the vast majority of the IPRs requested. *See* PTAB AIA Progress Statistics (3/6/14), Exh. 12.

Recognizing this reality, courts have stayed cases pending a decision from the PTAB

⁸ *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 737, 122 S. Ct. 1831, 1840, 152 L. Ed. 2d 944 (2002) (“When, however, the patentee originally claimed the subject matter alleged to infringe but then narrowed the claim in response to a rejection, he may not argue that the surrendered territory comprised unforeseen subject matter that should be deemed equivalent to the literal claims of the issued patent. On the contrary, ‘[b]y the amendment [the patentee] recognized and emphasized the difference between the two phrases[,] ... and [t]he difference which [the patentee] thus disclaimed must be regarded as material”).

whether to institute an IPR, presumably in part because of the high likelihood that an IPR will be instituted and the brief period of time it takes for the PTAB to issue an institution decision. *See, e.g., Capriola Corp.*, 2013 WL 1868344, at *3 (“if the PTO declines inter partes review, little time is lost, but if PTO grants inter partes review, the promise is greater for an important contribution by the PTO to resolution of the governing issues in the litigation”); *Neste Oil OYJ v. Dynamic Fuels, LLC*, C.A. No. 12-1744-GMS, 2013 WL 3353984, at *2 (D. Del. July 2, 2013) (unpublished) (granting stay before PTO instituted review because statistics reflected the likelihood of review); *Star Envirotech, Inc.*, 2013 WL 1716068, at *2 (rejecting plaintiff’s arguments attempting to discredit defendant’s prediction that the PTO will institute IPR and noting that amended standards for granting IPR likely result in further simplification of issues).

In an attempt to mislead the Court into thinking that BDSI’s IPR request is somehow flawed, Plaintiffs cite to two previous decisions declining to institute IPRs requested by BDSI without disclosing to the Court that those requests were declined solely on the basis of an alleged time bar, not on the merits, and that the alleged time bar at issue in those matters is not at issue in BDSI’s current petition,⁹ and therefore not relevant to the present action.

Nor is it relevant that only claims 15-19 of the ‘832 Patent are currently subject to a request for IPR. The decision not to challenge claims 1-14 in the IPR petition does not detract from the likelihood of issue simplification, because Plaintiffs cannot credibly assert claims 1-14 of the ‘832 Patent against BDSI in good faith – and even if they do, there is no chance of success. Moreover, even if Plaintiffs persist in their assertion of claims 1-14, the PTAB’s expert views on claims 15-19: (a) will simplify the issues presented with regard to claims 15-19 (*e.g.*,

⁹ In those petitions, BDSI requested IPR of amended claims that issued following reexamination. The PTAB concluded that BDSI’s requests for IPR were untimely, and therefore declined to institute the requested reviews solely on that ground, as opposed to the merits. *See generally* Exh. 13 and Exh. 14. The timeliness of BDSI’s ‘832 Patent IPR petition is not in question.

with regard to claim construction and validity); and (b) may clarify or simplify issues with regard to claims 1-14 (*e.g.*, it is unclear whether the claimed pH range of “about 3 to about 3.5” will be read into challenged claims 15-19 by the PTAB or Plaintiffs, *see, e.g.*, IPR Petition at 41 (D.I. 34-2) (“To the extent the pH range of about 3 to about 3.5 is read into the challenged claims...”). Therefore, regardless of whether claims 1-14 are asserted by Plaintiffs, the current IPR of claims 15-19 has potential to simplify issues in this litigation regarding all claims.

Given the potential for simplification and rulings that may impact all claims of the ‘832 Patent, and simplify the issues presented in this case, a stay is warranted. *See, e.g., Robert Bosch Healthcare Sys., Inc.*, 2013 WL 752474, at *4 (granting stay despite no PTO review of some patents and some claims because “there is no requirement that reexamination resolve all issues in a case in order to warrant a stay”); *Protectconnect, Inc. v. Leviton Mfg. Co.*, No. 10cv758, 2011 U.S. Dist. LEXIS 44045, at *10 (S.D. Cal. Apr. 22, 2011) (unpublished) (granting stay even though not all claims at issue were being reviewed by the PTO).

The cases relied upon by Plaintiffs do not support their position. The *Ultratec* case is not applicable because the decision turned on prejudice in the context of direct market competition rather than on simplification of issues. *Ultratec, Inc. v. Sorenson Commc’ns, Inc.*, No. 3:13-CV-0346-BBC, 2013 U.S. Dist. LEXIS 162459, at *12 (W.D. Wis. Nov. 14, 2013) (unpublished) (as “direct competitors in a small market... there is a greater likelihood that plaintiffs will lose significant market share to defendants”). The *Otto Bock*, *Davol*, and *Automatic* cases denied stays based on the totality of circumstances wherein prejudice resulted from direct competition of the parties (which is not the case here), and evaluated the stage of the litigation, the stage of the IPR, and the burden of proof in addition to the potential for issue simplification. *See Otto Bock HealthCare LP v. Össur hf*, No. 8:13-CV-00891-CJC, D.I. No. 110, at *4 (C.D. Cal. Dec.

16, 2013) (unpublished) (noting that prejudice to patentee is heightened when parties are direct competitors and that parties had already participated in significant discovery and motion practice); *Davol, Inc. v. Atrium Med. Corp.*, No. 1:12-CV-0958-GMS, 2013 U.S. Dist. LEXIS 84533, at *19 (D. Del. June 17, 2013) (unpublished) (finding that while ‘issue simplification’ and ‘stage of litigation’ factors favored a stay, “the court is concerned that Davol will suffer undue prejudice should it be forced to continue competing with Atrium's accused products”); *Automatic Mfg. Sys. v. Primera Tech., Inc.*, No. 6:12-CV-1727, 2013 U.S. Dist. LEXIS 67790, at *8 (M.D. Fla. May 13, 2013) (unpublished) (Court could not determine IPR scope and found that “a stay would unduly prejudice or present a clear tactical disadvantage to Plaintiff” that was in direct competition with defendant). Finally, the *IMAX* case involved claims completely unrelated to patent infringement, including state law, contract, and business law claims, which would not be simplified or narrowed by the PTO’s review of the patent claims. *See IMAX Corp. v. In-Three, Inc.*, 385 F. Supp. 2d 1030, 1031 (C.D. Cal. 2005). Such claims are not alleged here.

For these reasons and for the reasons set forth in BDSI’s Opening Memorandum, the requested IPR will simplify these proceedings, and therefore a stay is appropriate.

C. This Litigation is in its Infancy

Plaintiffs do not dispute that this case is in its earliest stages (Plaintiffs’ Opp. at 18), which weighs heavily in favor of a stay.

III. CONCLUSION

For the reasons set forth above and in BDSI’s Opening Memorandum, BDSI respectfully requests that this action be stayed pending the resolution of the *inter partes* review of the ‘832 Patent requested by BDSI.

Dated: March 13, 2014

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing DEFENDANT'S REPLY MEMORANDUM IN SUPPORT OF ITS MOTION TO STAY PENDING *INTER PARTES* REVIEW was filed, this March 13, 2014, via ECF which will send electronic notification to the following counsel of record for Plaintiffs:

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